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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,507	12/22/2004	Igor Stagljär	P2309US	6720
46002 7590 01/22/2007 JOYCE VON NATZMER Hall, Vande Sande & Pequigot, LLP 10220 River Road, Suite 200 Potomac, MD 20854			EXAMINER JOIKE, MICHELE K	
			ART UNIT	PAPER NUMBER
			1636	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/22/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/509,507	<b>Applicant(s)</b> STAGLJAR ET AL.	
	<b>Examiner</b> Michele K. Joike, Ph.D.	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 48-69 is/are pending in the application.
- 4a) Of the above claim(s) 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48-65 and 68 is/are rejected.
- 7) ☒ Claim(s) 66 and 67 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3. Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date ~~12/22/04~~  
9/01/05, 1/13/06, 1/20/06. 9/28/04

✓ ✓ ✓

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I in the reply filed on October 23, 2006 is acknowledged.

Claim 69 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 23, 2006.

Claims 48-69 are pending; claims 48-68 are examined.

### ***Priority***

This application repeats a substantial portion of prior Application PCT/EP03/03287, filed March 28, 2003, and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78. This relationship between the instant application and the parent application(s) must be recited, i.e. this application is a continuation-in-part of PCT/EP03/03287, filed March 28, 2003.

### ***Oath/Declaration***

This application presents a claim for subject matter not originally claimed or embraced in the statement of the invention. The new matter is in claim 68, which is

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drawn to a method of identifying a potentially pharmaceutically active agent with the ability to interfere with protein-protein interactions. While the specification teaches, for example, small compounds that block protein-protein interaction, there is no mention of any broadly identifying pharmaceutically active agents that interfere with protein-protein interactions. A supplemental oath or declaration is required under 37 CFR 1.67. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

### ***Specification***

The disclosure is objected to because of the following informalities: Sequences in paragraphs 86, 98, 99 and 105-114 of the specification are missing sequence identifiers.

Appropriate correction is required.

### ***Claim Objections***

Claims 66 and 67 are objected to because of the following informalities: Claim 66 depends on claim 1; which has been canceled. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-65 and 68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a first membrane bound protein or part thereof and a second protein or part thereof. The claims read on a broad genus of protein fragments.

The written description requirement for a genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicants were in possession of the claimed invention. In the instant case, the specification does not sufficiently describe a representative number of parts of proteins by actual reduction to practice or by disclosure of relevant identifying characteristics.

The specification only provides teachings of intact proteins. The specification does not teach how to screen for parts of proteins that will interact. The skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification because the specification only discloses the general protocol for the method and vector that will contain the proteins X and Y, but does not describe using a fragment of a protein that is very short in length such as one amino acid. The

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specification has not demonstrated that a very short fragment of the first membrane will be able to bind to the second test protein in the claimed method.

The state of the art at the time of filing does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the art that has shown using a single amino acid as a protein fragment in an assay for detection of protein-protein binding. Thus the skilled artisan cannot consult the art at the time of filing to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the state of the art at the time of filing teaches a structure-function relationship for a representative number of protein parts. As a result, the skilled artisan would not be able to envision the claimed invention. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

Claim 68 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 68 is drawn to a method of identifying a potentially pharmaceutically active agent with the ability to interfere with protein-protein interactions. While the specification teaches, for example, small compounds that block

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protein-protein interaction, there is no mention of pharmaceutically active agents that interfere with protein-protein interactions. This is a NEW MATTER rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 68 refers to a potentially pharmaceutically active agent. It is unclear what properties would make an agent "potentially" pharmaceutically active.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Stagljar et al (PNAS 95: 5187-5192, 1998, specifically pp. 5187, 5191 and figure 2).

Applicants teach a method and a kit for detecting the interaction between a membrane bound protein and another protein which can be membrane bound or soluble in a host cell that contains a detectable gene having a binding site for a transcriptional activator, introducing into the host cell a first chimeric gene encoding a test protein that is attached to a DNA sequence coding for a degradation protein module fused to a transcriptional activator and a second chimeric gene encoding a test protein which is either membrane bound or soluble that is attached to a DNA sequence coding a second



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degradation protein module and determining if the detectable gene of the host cell has been activated. The claims further limit the invention to yeast cells such as *S. cerevisiae*, the detectable gene being activated by an artificial activator such as protein A-LexA-VP16, the degradation protein modules are Cub and Nub, and the first test protein is a bacterial, viral, oncogene, growth factor or eukaryotic membrane protein.

Stagljar et al teaches a split-ubiquitin system for detecting the interaction between two membrane bound proteins by introducing and coexpressing plasmids that encode the fusion proteins Ost-1-Nub or Nub-Alg5 with Wbp1-Cub-PLV into *S. cerevisiae* strain yeast cells carrying *lacZ* and HIS3 reporter genes under the control of LexA-binding sites and testing cells for  $\beta$ -gal activity. The Ost1-Nub fusion protein consists of a portion of Ost1p ER membrane protein and the Nub module. The Nub-Alg5 fusion protein consists of the Alg5 ER membrane protein and the Nub module. The Wbp1-Cub-PLV protein consists of a portion of the Wbp1p ER transmembrane protein, the Cub module, and the PLV transcriptional activator (abstract, page 5187, right column, last paragraph to end of page 5189 and Figure 2). Thus, Stagljär et al teaches all the limitations of the recited claims. Stagljär et al teach all the features of claims 57-65 in combination, thereby anticipating the kit.

***Allowable Subject Matter***

No claims are allowed.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele K. Joike, Ph.D. whose telephone number is 571-272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele K Joike, Ph.D.  
Examiner  
Art Unit 1636

  
DAVID GUZO  
PRIMARY EXAMINER